UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/552,087	04/21/2000	Joseph R. Byrum	16517.132/38-21 (15786)B	4196

7590 04/01/2004

Monsanto Company
Lawrence M Lavin Jr
800 N Linbergh Boulevard
Mailzone N2NB
St Louis, MO 63167

EXAMINER	
SWITZER, JULIET CAROLINE	
ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 04/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
P.O. BOX 1450
ALEXANDRIA, VA 22313-1450
www.uspto.gov

Date mailed 04/01/04

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 0304

Application Number: 09/552,087
Filing Date: April 21, 2000
Appellant(s): BYRUM ET AL.

Thomas E. Holsten
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 1/12/04.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief. Appellant does not identify any related Appeals. However, it is noted that application 09/421106 is also on appeal, and a provisional double patenting rejection is pending between the instant application and the 09/421106 application.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

Appellant's brief includes a statement that claims 3, 5-7, 9, 10, and 12-20 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

No prior art is relied upon by the examiner in the rejection of the claims under appeal.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 101

1. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The pending claims have been reviewed in light of the Utility Examination Guidelines and Guidelines for Examination of Patent Applications under 35 U.S.C. 112, first paragraph, "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1092-1111, Friday, January 5, 2001.

Claims 3, 5-7, 9-10, and 12-20 are rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility.

The claimed subject matter is not supported by a specific, substantial, and credible utility because the disclosed uses are generally applicable to broad classes of this subject matter. In addition, further characterization of the claimed subject matter would be required to identify or reasonably confirm a "real world" use.

Rejected claims 3, 5-7, and 9-10 are drawn to plant host cells and transgenic plants that comprise construct having a promoter, wherein the promoter nucleic acid molecule comprises

SEQ ID NO: 1 or a complement thereof linked to a structural nucleic acid molecule and a 3' non-translated sequence that functions in said cell to cause termination of transcription.

Claims 12-20 are drawn to substantially purified nucleic acid molecules that comprise instant SEQ ID NO: 1 or a nucleic acid sequence that is related to instant SEQ ID NO: 1 by a percent identity. Thus the claims encompass SEQ ID NO: 1 and many, many variants of the sequence.

A well-established utility is defined as a specific, substantial and credible utility which is well known, immediately apparent or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art. The instant host cells and transgenic plants do not have a well established utility because the art does not teach any utility for the instantly host cells and transgenic plants that is specific, substantial, and credible.

The specification discloses a number of general utilities for the nucleic acids disclosed herein. For example, the specification generally discloses that these nucleic acids are useful in genetic mapping studies (p. 35), physical mapping (p. 43), contig mapping (p. 46), comparative mapping (p. 49-56), the identification of polymorphisms (p. 49-56), monitoring expression (p. 56), locating regions of identity by descent between individuals (p. 58), isolating clones (p. 59), microarray based methods (p. 60), direct site mutagenesis (p. 60), transformation (p. 62-80), in cosuppression (p. 80), to reduce gene function (p. 82), and as antibodies (p. 83). None of these asserted utilities are specific because the disclosed uses of the nucleic acids are generally applicable to any nucleic acid and therefore are not particular to the nucleic acid sequences being claimed.

The instant specification herein discusses transformation of cells and plants in general (p. 62-80), but does not discuss these methodologies with regard to SEQ ID NO: 1 in particular. The specification in table 1 sets for the that the protein encoded by instant SEQ ID NO: 1 has 50% identity with a putative POL3 protein from Arabidopsis, but the specification does not assert a utility for SEQ ID NO: 1 or the protein encoded by SEQ ID NO: 1 based on this homology. The fact that SEQ ID NO: 1 encodes a polypeptide that has homology to a "putative" protein suggests that the functionality of the Arabidopsis protein has not been confirmed. Thus, further experimentation would be required to reasonably confirm the identity of the protein both for Arabidopsis and for Glycine max proteins. Beyond that, further experimentation would still be required to establish a real world utility for such a protein. Further still, the claims encompass nucleic acids are related to SEQ ID NO: 1 by as little as 70% identity, but the specification provides no guidance as to which portions of the protein comprising SEQ ID NO: 1 would retain whatever functionality and utility possessed by the polypeptide encoded by SEQ ID NO: 1.

Claims 3, 5-6, 7, 9, and 10, are drawn to transformed plant cells and transgenic plants that have a construct which contains instant SEQ ID NO: 1 or its complement as "an exogenous promoter region" that functions in a plant cell to cause the production of an mRNA molecule. Thus, these claims suggest that SEQ ID NO: 1 is being included in the host cells and transgenic plants of claim 3, 5, and 6 for its functionality as a "promoter." This is not considered a substantial utility because further experimentation would be required to reasonably confirm that SEQ ID NO: 1, or its complement, or fragments of either would function as a promoter as required by the claims. The specification does not provide any guidance as to the use of SEQ ID NO: 1, its complement or fragments thereof as promoters. In order to use the claimed invention,

one would first have to confirm that either SEQ ID NO: 1 or its complement is in fact a promoter, then determine which fragments are also promoters. One would have to determine the type of promotion conferred by SEQ ID NO: 1, that is, one would have to determine if the promotion is tissue specific or constitutive, for example, or if it is an inducible promoter, and under what circumstances it is induced or repressed in order to make use of the claimed plants. Each of these determinations is highly unpredictable, from the determination as to whether or not SEQ ID NO: 1 or its complement is in fact a promoter to the determination of the type of promoter it may be to the determination of fragments of the promoter that confer promotion activity.

No specific function of the polypeptide encoded by SEQ ID NO: 1 has been provided, nor has it been demonstrated that SEQ ID NO: 1 has any utility as a marker for a specific phenotypic trait. There has been no specific assertion that in fact SEQ ID NO: 1 is a promoter, aside from the claims. The specification has not provided any guidance as to the use of SEQ ID NO: 1 as a promoter. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities, and this is particularly the case with regard to correlation with phenotypic traits or genetic mapping of phenotypic traits. Further, the use of the instantly disclosed polynucleotides to produce the protein encoded by the nucleic acid is not a specific or substantial utility since there is no known utility for the polypeptide. The use of instant SEQ ID NO: 1 as a promoter is not a specific or substantial utility since further experimentation would be required to confirm that in fact SEQ ID NO: 1 has the ability to cause the production of an mRNA molecule and the conditions under which such activity occurs. Thus, no utility has been described for the transformed plant cells

and transgenic plants comprising SEQ ID NO: 1, either as a promoter or as a structural nucleic acid encoding a protein. The specification has provided not information as to what effect the expression of SEQ ID NO: 1 in a transgenic plant would have on the plant. After further research, a specific and substantial credible utility might be found for the claimed cells and plants. This further characterization, however, is part of the act of invention and until it has been undertaken, Applicant's invention is incomplete.

As noted by Brenner v. Manson, 383 U.S. 519, 535-536 (1996), "Congress intended that no patents be granted on a chemical compound whose sole "utility" consists of its potential role as an object of use-testing...a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." Neither the specification as filed nor any art of record discloses or suggests any property or activity for the claimed cells and plants such that another non-asserted utility would be well established for the compounds.

For these reasons, the claimed host cells and transgenic plants are not supported by either a specific and substantial asserted utility or a well established utility. Note, because the claimed invention is not supported by a specific and substantial asserted utility for the reasons set forth above, credibility has not been assessed.

Claim Rejections - 35 USC § 112, 1st paragraph

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3, 5-7, 9-10, and 12-20 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

For all the above reasons, the disclosure is insufficient to teach one of skill in the art how to use the invention. A review of *In re Wands,* 8 USPQ2d 1400 (CAFC 1988) clearly points out the factors to be considered in determining whether a disclosure would require undue experimentation and include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and, (8) the breadth of the claims. All of these factors are considerations when determining the whether undue experimentation would be required to use the claimed invention. As is evidence in the discussions *supra*, each of these factors has been carefully considered in the instant grounds of rejection, and it is maintained that undue experimentation would be required by the skilled artisan to use the instant invention.

Claim Rejections - 35 USC § 112

3. Claims 12-19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to nucleic acids which comprise SEQ ID NO: 1 or a nucleic acid related to SEQ ID NO: 1 by a particular range of identity (i.e. 100% to 80% identity, as in claim

13). This genus is sufficiently broad so as to encompass a multitude of variants of SEQ ID NO: 1, as well as any full length coding sequence, mRNA, promoter, or genomic DNA of which SEQ ID NO: 1 is a portion, or of which the recited polynucleotides with identity to SEQ ID NO: 1 are portions. This large genus is represented in the specification by one species, a nucleic acid consisting of SEQ ID NO: 1. Thus, applicant has express possession of only one species in a genus which comprises hundreds of millions of different possibilities. Claim 17 further recites that the molecule comprises a region having a single nucleotide polymorphism. The specification does not describe a single example of such a polymorphism within SEQ ID NO: 1.

The claims do not recite any correlative structure/function relationship that defines the claimed invention.

With regard to the written description, all of these claims encompass nucleic acid sequences different from those disclosed in the specific SEQ ID No:s which, for claims 12-15 and 17-19 include modifications by permitted by the % identity language for which no written description is provided in the specification.

> It is noted that in Fiers v. Sugano (25 USPQ2d, 1601), the Fed. Cir. concluded that "...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

In the instant application, only the nucleic acid sequence of the disclosed SEQ ID Nos are described. Also, in Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that:

> "...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

In the application at the time of filing, there is no record or description which would demonstrate conception of any proteins modified by addition, insertion, deletion, substitution or inversion with the disclosed SEQ ID No: 1 but possessing one or more nucleotide differences such that a different amino acid sequence is encoded which retains the function of the nucleic acid consisting of SEQ ID NO: 1.

(11) Response to Argument

Appellant's arguments drawn to the above rejections have been considered, however, are not found persuasive for the following reasons. The paragraph numbers used in the response to argument section follow those used in the Brief.

8.A – Appellant summarizes a portion of *Brenner v. Manson* which includes the allegation that Appellant has met their part of the bargain in that the claimed nucleic acid molecules supply the benefit to the public of the ability to identify the presence or absence of a polymorphism in a population of soybean plants. Appellant further allege that this is a specific and substantial "real world" benefit. In response, a myriad of polymorphisms are known to occur in nucleic acid molecules in plants etc., both of the silent type as well as those which result in significant phenotypic effects. Appellant has not set forth any information which specifies whether polymorphisms, if detected via the instantly claimed invention, via hybridization, for example, correlates with anything of significance whatsoever. Thus, there is neither a specific nor substantial utility for such polymorphism detection. Further research would be required to

determine what said detection of polymorphism indicates. This need for further research also supports the lack of currently available form of utility.

Appellant then argues that Appellants have produced an adequate description of the claimed nucleic acids which would demonstrate that Appellant had possession of the claimed invention. Appellant states that for each genus of claimed nucleic acid molecules, *i.e.*, the nucleic acid molecules comprising the nucleic acid sequences of SEQ ID NO: 1 and their complements, has been described by recitation of the common structural feature which distinguishes molecules in the genus from molecules not in the claimed genus. In response, it should be noted that SEQ ID NO: 1 does not contain a complete open reading frame. If it were so, Appellant would have indicated. Because claims rejected for lack of written description are drawn a nucleic acid comprising a nucleic acid sequence of SEQ ID NO: 1, such claim language would embrace a full-length cDNA (containing a complete open reading frame), rendering the claimed genus lacking proper written description.

8.B – Appellant summarizes the lack of utility rejection and alleges that this is erroneous in the first paragraph in this section. This argument is again an allegation without arguing the specifics of the rejection and is thus non-persuasive and reasonably an introductory summary by Appellant (p. 5).

Appellant argues that the lack of utility analysis misstates the asserted uses, ignores disclosed utilities, and misapplies the doctrine of "practical utility" (paragraph bridging p. 5-6) This argument is again an allegation without arguing the specifics of the rejection and is thus non-persuasive and reasonably an introductory summary by Appellant.

Appellant summarizes a test for utility directed to an "identifiable benefit." Appellant argues that identifiable benefits are provided in the specification, for example, use as regulatory elements, identification of polymorphisms, and use as a hybridization probe for monitoring expression. None of these are specifically applied in the specification to the nucleic acid claimed in claims 12-20, nor to the transgenic cells and plants of claims 3, 5-7, and 9-10. Any discussion of these utilities in the specification is generic in nature. It is not established in the specification if the nucleic acid of the claimed invention is a coding nucleic acid (thus expressed, and could be detected in an expression assay) or a regulatory element. All discussion of polymorphisms in the specification is generic in nature, suggesting that the polymorphisms and microsattelites to be identified may exist, but none are identified. The specification lacks a discussion of any specific or substantial phenotypic association or even predisposition regarding any claimed nucleic acid. This lack of such association can only be remedied, if such an association with any phenotype even exists for the instantly claimed nucleic acids, by further research. It is also unknown what such research may or may not find regarding the instantly claimed nucleic acid molecules. This supports the lack of a currently available utility for the instantly claimed invention as is the basis for the lack of utility rejection against the instant claims. Then the specification further teaches a marker utility for the instant invention. Procedures for marker usage include expression profiling but the specification again discusses these only generically without any association or even vague connection to the instantly claimed invention. Thus these generic procedural guidelines lack specificity as well as substantiality regarding the utility of the instantly claimed invention which is directed to a particular set of nucleic acids and therefore non-persuasive. Furthermore,

it is noted that the rejected claims include transformed plant cells and transgenic plants and the discussion in this section of the Brief does not address these.

8.B(1) – Appellant points out that the specification discloses utilities of measuring the level of mRNA in a sample and use as molecular markers. As addressed, these utilities can broadly be applied to any nucleic acid and do not provide a specific and substantial utility for the claimed nucleic acid, cells, or plants.

8.B(1)(a) – Appellant again in this section points to polymorphism identification as an asserted utility and point again to pages 49-56 of the instant specification, which generically discusses polymorphisms and polymorphism detection. Appellant argues that the disclosed utilities are directly analogous to the utilities of a microscope to locate and measure nucleic acids within a sample, cell, or organisms, and also indicates a comparison to gas chromatographs, etc. In response, a microscope, a gas chromatograph, etc. have well established utilities where known analyses are available with a clearly useful result. These tools are used to analyze a wide variety of samples that are subjected to the appropriate analysis. A microscope can be used to view any tissue sample from any organism, yet the claimed nucleic acids can be used only to detect themselves. A microscope, for example, is a well known diagnostic tool for cancer detection in biopsy samples. A gas chromatograph is well known to be useful for detection of toxic material, for example, as also summarized by Appellant in the footnote of page 8 of the Brief. These uses are well known and beneficial in that results are already determined which are useful for at least one analysis type. No comparable well known use(s) have ben set forth or are known for the instantly claimed invention. No already determined analysis result is known for the instantly claimed invention. Only further research, may, not necessarily, but may result in some

determinable result which is beneficial. Thus, the microscope etc. is not analogous to the instant invention as there is no well known use(s) for the instant invention other than for further research to find a use thus supporting the lack of utility rejection.

Appellant then argues that the absence of a polymorphism demonstrates a common genetic heritage between two populations. No polymorphism is disclosed in the instant application. Further, genetic heritage is determined via significantly large profiles of many polymorphic sites, a single polymorphism being insufficient. Thus, Appellant's allegation of this utility being in currently available form is non-persuasive. Even if a particular single polymorphic site may be a minimal suggestion of a common heritage, this has neither been investigated nor established by the instant disclosure for any of the claimed nucleic acid molecules. Thus, this is an allegation without factual support and therefore also non-persuasive.

8.B(1)(b) – Appellant argues that the asserted utility of a probe or primer source is substantial because the specification discloses that the claimed nucleic acid can be used to isolate nucleic acid from a variety of other plant species. However, this is not persuasive as this is not a specific utility for the claimed nucleic acid as any nucleic acid could be attributed such a utility. Furthermore, it is not substantial because even if such nucleic acids could be isolated, one still would not know how to used the isolated nucleic acid. For example, is it a promoter or coding portion of a gene? Appellant argues that isolation of a promoter is an example of a disclosed utility. In response, there is no indication of what utility results or is promoted, even if a promoter was isolated by the chromosome walk, as argued by Appellant. Further research would be required to characterize such a promoter as to what may or may not activate it. Thus, again

further research would be required to define a specific and/or substantial utility for the claimed nucleic acid molecules which supports this lack of utility rejection.

8.B(1)(c) – Appellant points out that the specification discloses that the claimed nucleic acid molecules have promoter regions or partial promoter regions. However, this disclosure does not provide particular guidance for instant SEQ ID NO: 1, and furthermore, applellant's own statement highlights part of the lack of information- is SEQ ID NO: 1 a promoter region or a partial promoter region? How does it promote transcription, under what conditions, for example? Further experimentation would be required to reasonably confirm this asserted utility, and therefore it is maintained that this utility is not a substantial utility.

8.B(2) – Appellant summarizes some legal issues regarding "substantial" utility, and the asserts that there can be no question that one skilled in the art can use the claimed nucleic acid molecules in a manner which provides an immediate benefit to the public, for example to detect the presence or absence of polymorphisms (Brief, p. 12). However, the specification does not teach any polymorphisms within the claimed sequence, host cells, or transgenic plants that can be detected with instant SEQ ID NO: 1, and thus further experimentation would be required to reasonably confirm and practice this putative utility. There is no evidence of record which leads one to any putative polymorphisms that can be used by a breeder to determine the genetic distribution of parental genetic material.

Appellant further argues that there is no question that the public has recognized the benefits provided by the claimed subject matter, however, applicant does not provide any specific arguments with regard to the claimed subject matter, only a general commentary about EST molecules. This is not persuasive because it does not overcome the fact that the

specification does not provide any utility that does not require further experimentation to reasonably confirm that it is in fact applicable in a specific manner to the instantly claimed subject matter.

Appellant argues that a multi-million dollar industry has been established for ESTs which may also find utility as industrial products for fermentation processes. In response, there is no instant support for the instantly claimed nucleic acid molecules being of monetary value. For fermentation utility, some type of specific and substantial fermentation usefulness would be required. No such specific or substantial utility has been even asserted for fermentation usage. Further research again would be required to determine the result of the presence of the instantly claimed nucleic acid molecules in fermentation processes, such as in bacteria or plants being fermented. This need for further research again supports the lack of utility rejection.

Appellant argues that the market participants for EST products are primarily sophisticated corporations with highly knowledgeable scientists. In response, no market value has been determined or even alleged for the instantly claimed nucleic acids. Thus, the allegation of such value is without factual support and non-persuasive. It is also pointed out that ESTs in such markets are valued in large sets of ESTs and not singly unless some specific and substantial utility for a particular EST is known. Thus, the instantly claimed nucleic acid molecules do not correspond to such large sets of ESTs as sold either in sequence information form or as combinatorial sets thus making this argument non-persuasive.

8.B(3) – This section argues that the credibility issues is generally directed to "hare-brained" utilities or wholly inoperative inventions. In response, the lack of utility rejection is based on a lack of either a well established utility or a specific, substantial, and credible utility

with credibility not being assessed. It is acknowledged that polymorphism analysis, for example, are credible utilities, but that a lack of utility still exists if there is no well established utility or either a specific or substantial utility as is the situation for the instantly claimed invention.

8.C – Appellant argues that the disclosure of the instant specification meets the Wands factors, and thus is fully enabled by the specification. The enablement rejection is based on the fact that no patentable utility has been set forth for the claimed invention, and thus, one would not know how to use the claimed invention based on the disclosure of the specification. Though it is clear from the specification that one would know how to "make" the claimed invention, the rejection is maintained for the reasons of record as to the fact that the specification does not provide how to use the claimed invention.

Nonetheless, appellant's arguments are addressed. Appellant argues that the specification sets forth nucleic acid molecules and methods of use thereof (p. 16, second and third paragraphs). These methods of use thereof have been thoroughly discussed in the utility rejection and related arguments, and it is maintained that no specific and substantial utility is provided in the specification for the claimed nucleic acids and constructs comprising the nucleic acids. Appellant further argues that practitioners are guided by considerable knowledge and resources to introduce into other hosts nucleic acid sequences, and that the art is highly unpredictable. The ability to actually introduce the instantly claimed nucleic acid sequence into a host is not in question, however the effect that would result from such introduction is entirely unknown, as it is unknown what function instant SEQ ID NO: 1 has in vivo. Some of the claims set forth that SEQ ID NO: 1 is a promoter, yet the specification provides no guidance as to what

type of promotion can be expected, under what circumstances, etc. Each of these factors is entirely unpredictable.

It is maintained that due to the lack of utility set forth for the claimed invention, the rejection under 112 1st paragraph for lack of enablement is proper as one would not know how to use the claimed invention.

8.D – Appellant states that Appellants need not describe every nuance of the claimed invention when using the transitive language, "comprising." Appellants continue that the specification demonstrates to one skilled in the art that Appellant was in possession of the claimed general of nucleic acid molecules. Appellants specific arguments are produced in the following section 8.D(1).

8.D(1) and (2) – Appellants argue that they have provided the nucleic acid sequence required by the claims, *i.e.*, SEQ ID NO: 1 and vectors comprising these nucleotide sequences, and therefore have established possession of the claimed invention. The claimed invention, which is drawn to a polynucleotide *comprising* the above SEQ ID NO: 1, when the specification only discloses a partial sequence, as well as partial open reading frame, effectively encompasses a full-length cDNA sequence comprising a full open reading frame. While it is acknowledged that Appellant need not describe "every nuance" of the claimed invention, the written description must bear a reasonable correlation to that which is claimed. The disclosed subgenus and species embraced by the claims are not representative of the entire genus being claimed. The genus of nucleic acid molecules being claimed embraces any and every type of nucleic acid molecule that comprises instant SEQ ID NO: 1, and additional sequences of any size and sequence, not just vector backbones. Clearly, at the time of filing, Appellant was not in possession of genomic

materials that contain the common EST fragment, which are embraced by the open-ended claims.

Additionally, one skilled in the art would reasonably conclude that the claims embrace full length mRNAs, cDNAs and genomic sequences, and the specification provides no physical (i.e. structural) characteristics of these molecules to distinguish them from other nucleic acid molecules comprising the claimed SEQ ID NO: 1, and no other indication that would suggest Appellant possessed them. This particular subgenus embraced by the claims has a disclosed potential utility not possessed by those members of the claimed genus useful only in hybridization. Full length mRNAs, cDNAs and genomic sequences (genes) would encode a corresponding protein(s).

A fundamental issue here is specific to the very narrow class of product that is nucleic acid molecules. The basic question upon which Appellants and the Examiner disagree is whether the disclosure of a partial sequence of nucleic acid molecules that may encode a corresponding protein is sufficient to establish possession of a broad genus based solely on the description of the partial sequence.

> As stated in *University of California v. Eli Lilly and Co.* at page 1404:
> An adequate written description of a DNA ... "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." *Id.* at 1170, 25 USPQ2d at 1606.

That Appellants claims embrace nucleic acid molecules that encode a corresponding protein, is clearly evident from the claim language chosen. The Court in *University of California v. Eli Lilly and Co.*, at page 1405, further noted regarding generic claims:

> A written description of an invention involving a chemical genus, like a description of a chemical species, "requires a precise definition, such as by structure, formula, [or] chemical name," of the claimed subject matter sufficient to distinguish it from other materials. *Fiers*, 984 F.2d at 1171, 25 USPQ2d at 1606; *In re Smythe* , 480 F.2d 1376, 1383, 178 USPQ 279, 284-85 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus. . . .").

In the instant case, the only species specifically enumerated is the nucleic acid of SEQ ID NO: 1. The specific embodiments that in addition to these sequences include nucleic acids that will allow the corresponding protein to be encoded cannot be predicted without the coding sequence itself. This coding sequence ***has not been*** disclosed. Clearly, the specification would not show one skilled in the art that the these desired subcombinations were possessed by Appellant, and thus the embracing genus was also not possessed.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Juliet Switzer
March 27, 2004

Conferees
W. Gary Jones
Gary Benzion

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600

MONSANTO COMPANY
LAWRENCE M LAVIN JR
800 N LINBERGH BOULEVARD
MAILZONE N2NB
ST LOUIS, MO 63167

GARY BENZION, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600